

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

ORIZIT PAED 75/50 (dispersible tablet)

Rifampicin 75 mg and isoniazid 50 mg

Sugar free.

Contains 3,13 mg aspartame

Read all of this leaflet carefully before you start taking ORIZIT PAED 75/50

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **ORIZIT PAED 75/50** has been prescribed for your child personally and you should not share your child's medicine with other people. It may harm them, even if their symptoms are the same as your child's.

What is in this leaflet

1. What **ORIZIT PAED 75/50** is and what it is used for
2. What you need to know before you take **ORIZIT PAED 75/50**
3. How to take **ORIZIT PAED 75/50**
4. Possible side effects
5. How to store **ORIZIT PAED 75/50**
6. Contents of the pack and other information

1. What ORIZIT PAED 75/50 is and what it is used for

ORIZIT PAED 75/50 is an antimicrobial medicine used in the treatment of pulmonary tuberculosis (TB infection in the lungs) in children.

2. What you need to know before you give **ORIZIT PAED 75/50**

Do not take ORIZIT PAED 75/50 if your child suffers from any of the conditions mentioned below:

- If your child is hypersensitive (allergic) to rifamycins including rifampicin, isoniazid or other chemically-related medicines such as ethionamide, pyrazinamide, niacin or to any of the ingredients contained in **ORIZIT PAED 75/50**. (listed in section 6).
- If your child has any kind of liver disease or jaundice (yellowing of the eyes and skin).
- **ORIZIT PAED 75/50** should not be given with nevirapine, saquinavir and ritonavir (used in HIV treatment).
- Your child has any kidney disease.
- Your child has porphyria.
- Your child has a history of gout.
- Your child is diabetic
- Your child has epilepsy
- If your child develops thrombocytopenia and purpura while taking **ORIZIT PAED 75/50** (bruising, nosebleeds or bleeding in the mouth and gums, rash with pinpoint red spots).
- If your child is pregnant or breastfeeding her child.

If your child develops itching with swelling or skin rash or difficulty breathing, or if the skin and eyes turn yellow while taking **ORIZIT PAED 75/50**, do not give any more **ORIZIT PAED 75/50** and tell your doctor immediately.

Warnings and precautions

Take special care with **ORIZIT PAED 75/50**

- Before you give **ORIZIT PAED 75/50**, tell your doctor if your child has epilepsy.
- **ORIZIT PAED 75/50** should not be given to children whose liver is not functioning normally, however, in cases where there are no other treatment options your doctor will monitor your child's liver function before treatment and every two to four weeks during treatment with **ORIZIT PAED 75/50**.

Tell your doctor immediately and stop giving **ORIZIT PAED 75/50** if your child develops symptoms of hepatitis (inflammation of the liver, if left untreated, could lead to serious consequences) such as fatigue, weakness, feeling unwell, loss of appetite, nausea or vomiting.

- Your doctor will be monitoring your child's blood counts if your child has liver disease or is on long-term treatment with **ORIZIT PAED 75/50**. If your child develops low platelet counts (blood cells responsible for clotting) with symptoms of easy or excessive bruising, bleeding into the skin that appears as a rash of pinpoint-sized reddish-purple spots usually on the lower legs, prolonged bleeding from cuts, spontaneous bleeding from the gums or nose and blood in urine or stools, then **ORIZIT PAED 75/50** should not be given and be permanently withdrawn (see Do not take).
- If other serious complications due to the medicine occur such as kidney failure, or blood diseases, **ORIZIT PAED 75/50 should be stopped and never restarted.**
- Urine, faeces, saliva, sputum, sweat and tears may be coloured red-orange by **ORIZIT PAED 75/50**.
- Your doctor may prescribe additional blood tests to monitor your child's adrenal hormone, thyroid hormone and vitamin D levels.
- Soft contact lenses may be permanently stained.
- Your doctor may prescribe periodic eye examinations as **ORIZIT PAED 75/50** may cause blurred vision or loss of vision with or without eye pain and may also cause irritation of the eyes.
- Your doctor may prescribe Vitamin B₆ (pyridoxine) with **ORIZIT PAED 75/50** to minimise adverse reactions if your child is malnourished or has neuropathy (damage to the nerves resulting in poor coordination, muscle weakness, pain in the fingers or toes, or numbness).
- Give **ORIZIT PAED 75/50** to your child as prescribed by your doctor on a continuous basis without interruption to avoid developing side effects such as a serious allergic reaction (swelling of the hands, feet, ankles, lips, mouth or throat, which may cause difficulty in breathing, rash and itching) or a "flu-like" syndrome (chills, dizziness, difficulty breathing, fever, headache, muscle pain, bone pain and shivering).

Other medicines with and ORIZIT PAED 75/50

Always tell your health care provider if your child is taking any other medicine. (This includes all complementary or traditional medicines).

ORIZIT PAED 75/50 may change the effect of other medicines and other medicines may change the effect of **ORIZIT PAED 75/50**.

Do not give ORIZIT PAED 75/50 and tell your doctor if you are taking the following medicines:

- Nevirapine, saquinavir and ritonavir (HIV medicines).

The following medicines can make **ORIZIT PAED 75/50** work less well:

- Alcohol, alfentanil (for pain during surgery), aminosalicic acid (TB medicine), corticosteroids such as hydrocortisone, betamethasone and prednisolone (for treating inflammatory conditions), ketoconazole (for fungal infections), propranolol (for high blood pressure) and high doses of pyridoxine (vitamin B6).
- Antacids containing magnesium trisilicate, aluminium hydroxide or sodium bicarbonate and other aluminium containing antacids for indigestion. Give **ORIZIT PAED 75/50** at least 1 hour before the antacid.

When you are giving **ORIZIT PAED 75/50**, it is especially important to tell your doctor or healthcare professional if you are taking any of the following medicines as your doctor may have to adjust the dose of the medicine:

- Medicines used to treat epilepsy such as ethosuximide, phenytoin and carbamazepine.
- Medicines such as itraconazole, fluconazole and ketoconazole used for treating fungal infections.
- HIV medicine such as zidovudine, delavirdine, efavirenz, HIV-protease inhibitors (lopinavir, duranavir, atazanavir, fosamprenavir, indinavir).
- Other medicines include certain anaesthetic medicines (to relax muscles prior to surgery), azathioprine, ciclosporin (immune suppressants), chloramphenicol, cycloserine, dapson, doxycycline (medicines used for infections), cimetidine (used to treat ulcers), clofibrate (lowers cholesterol), corticosteroids such as hydrocortisone, betamethasone and prednisolone (for treating inflammatory conditions), warfarin (thins blood), diazepam, (for anxiety and depression), haloperidol (for mental illness), hexobarbitone (sedative), methadone (for heroin withdrawal), oral hypoglycaemic medicines used in diabetes

treatment), sulphasalazine (used for rheumatoid arthritis and inflammatory bowel disease), Thyroid hormones (levothyroxine), theophylline (for wheezing or difficulty in breathing), quinine (used in malaria), medicines to control your heartbeat such as digoxin, disopyramide, lorcainide, mexiletine, propafenone, quinidine, tocainide, medicines to treat heart problems such as beta blockers (propranolol), verapamil and other calcium channel blocking medicines, medicines used for severe pain such as codeine, morphine, fentanyl or pethidine, medicines used for pain and fever such aspirin and medicines to help you sleep known as barbiturates (e.g. phenobarbitone).

- **ORIZIT PAED 75/50** may decrease the effectiveness of oral contraceptives. Use a reliable barrier method of contraception such as condoms while taking **ORIZIT PAED 75/50**.

The following when taken with **ORIZIT PAED 75/50** may increase the incidence of side-effects:

- Medicines used to treat epilepsy such as ethosuximide, phenytoin, primidone and carbamazepine (your doctor will adjust the dose of the epilepsy medication accordingly)
- HIV medicine such as HIV-protease inhibitors (lopinavir, ritonavir, saquinavir, duranavir, atazanavir, fosamprenavir), stavudine and zalcitabine.
- Other medicine such as warfarin (thins blood), diazepam, triazolam (for anxiety and depression), cycloserine (TB medicine), disulfiram (treatment of alcohol dependence), theophylline (for wheezing or difficulty in breathing).
- Alcohol (daily consumption could lead to severe liver problems).

ORIZIT PAED 75/50 with food, drink and alcohol

- **ORIZIT PAED 75/50** may interact with tyramine-containing foods (cheese, red wine) and to foods containing histamine (e.g. skipjack, tuna, other tropical fish) resulting in headache, sweating, palpitations (heart beating too hard or too fast), flushing and low blood pressure. Avoid giving tyramine- and histamine-containing foods to your child while on treatment with **ORIZIT PAED 75/50**.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have

a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnancy:

Safety during pregnancy has not been established.

Breastfeeding:

Safety during breastfeeding has not been established.

Driving and using machines

ORIZIT PAED 75/50 may cause dizziness, impaired concentration, and/or drowsiness. If you experience these symptoms, avoid potentially hazardous tasks such as driving or operating machinery.

ORIZIT PAED 75/50 contains aspartame

ORIZIT PAED 75/50 contains 3,13 mg aspartame in each tablet.

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to give ORIZIT PAED 75/50

Do not share medicines prescribed for you with any other person.

Always give **ORIZIT PAED 75/50** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of **ORIZIT PAED 75/50** is too strong or too weak, talk to your doctor or pharmacist.

ORIZIT PAED 75/50 is recommended in the continuation phase of the treatment of pulmonary tuberculosis. **During this phase ORIZIT PAED 75/50 should be taken continuously on a daily basis.**

Your doctor will prescribe the required number of tablets to be given on a daily basis based on your child's body weight.

The tablets can either be dispersed in as little as 5 ml of water, or chewed, and should preferably be taken on an empty stomach (30 minutes before or 2 hours after a meal) as a single dosage. **ORIZIT PAED 75/50** should be given at least 1 hour before aluminium containing antacids are taken.

If you give more ORIZIT PAED 75/50 than you should

In the event of overdosage consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control center.

Symptoms include nausea, vomiting, stomach pain, dizziness, high blood sugar levels, high levels of acid in the blood, hallucinations, difficulty in breathing and central nervous system depression with seizures and coma. Other signs of overdosage includes bright-red discolouration of the skin and mucous membranes, decreased mental alertness, swelling of the face and “puffy eyes” and generalised itching.

If any of the above symptoms occur, get medical help immediately by calling your nearest doctor or healthcare professional.

If you forget to give your child ORIZIT PAED 75/50

If your child has missed a dose of **ORIZIT PAED 75/50** give it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and go back to your regular scheduling. Never double the dose.

If you stop giving your child ORIZIT PAED 75/50

If the full treatment prescribed by your doctor is not completed, some of the bacteria causing the TB infection may not be killed. These bacteria may continue to grow and multiply so the TB infection may not clear completely or it may return.

4. Possible side effects

ORIZIT PAED 75/50 can have side effects.

Not all side effects reported for **ORIZIT PAED 75/50** are included in this leaflet. Should your child's general health worsen, or if your child experiences any untoward effects while taking **ORIZIT PAED**

75/50, please consult your health care-provider for advice.

If any of the following happens, stop taking **ORIZIT PAED 75/50** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting
- yellowing of the skin and eyes, also called jaundice

These are all very serious side effects. If you have them, you may have had a serious reaction to **ORIZIT PAED 75/50**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Red and/or itchy skin, blisters or pimples.
- Skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (symptoms of Stevens Johnson Syndrome).
- Widespread scaling of the skin with itching, skin redness and hair loss (symptoms of exfoliative dermatitis).
- Shortness of breath and wheezing.
- Lung disease causing coughing, difficulty breathing and wheezing (symptoms of pneumonitis).
- Scarring and thickening in the lungs with shortness of breath (symptoms of pulmonary fibrosis).
- Blood in the urine or any other urination disturbances.
- Fever, chills, headache or dizziness.
- Bone pain.
- Bruising, nosebleeds or bleeding in the mouth and gums, rash with pinpoint red spots.
- Fatigue, weakness, malaise (feeling unwell), anorexia (loss of appetite), nausea or vomiting.

- Abdominal pain, blood in the stool, ongoing bouts of diarrhoea that do not respond to over-the-counter (OTC) medicines or an unexplained fever lasting more than a day or two (symptoms of ulcerative colitis).
- Bleeding from the stomach wall with vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea.
- Inflammation of the pancreas with severe upper stomach pain, nausea and vomiting.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor immediately if your child has any of the following side effects, particularly if they occur several weeks after stopping treatment with ORIZIT PAED 75/50:

- Severe stomach cramps.
- Watery and severe diarrhoea, which may also be bloody.
- Fever, in combination with one or both of the above.

You child may have a serious condition affecting the bowel, which may need urgent medical attention.

Do not give any diarrhoea medicine without first checking with your doctor.

Tell your doctor if you notice any of the following:

Frequently occurring side effects:

- Heartburn, anorexia, nausea, vomiting, wind, cramps or diarrhoea, constipation, dry mouth.
- Skin reactions with flushing and itching, with or without a rash.
- Aching muscles, muscle tenderness or weakness, not caused by exercise.
- Reddish-orange to reddish-brown discolouration of the urine, faeces, saliva, sputum, sweat and tears.
- Soft contact lenses may be permanently stained.
- Numbness or weakness of the arms and legs.
- Increase in liver enzymes.

Less frequent side effects:

- Increase in some white blood cells (eosinophilia).

- Lack of white blood cells resulting in frequent infections such as fever, severe chills, sore throat or mouth ulcers (leucopenia).
- Tiredness, headaches, being short of breath when exercising, dizziness, looking pale and yellowing of the skin and/or eyes (haemolytic anaemia).
- High blood glucose levels.
- High levels of acid in the blood.
- Mental illness with strange or disturbing thoughts or moods.
- Loss of memory.
- Headache, dizziness, drowsiness, fatigue, inability to concentrate or confusion.
- Poor coordination, pain in the fingers or toes, or numbness, unusually increased reflexes or twitching.
- Fits or increase in fits if you are an epileptic patient.
- Blurred vision or loss of vision with or without eye pain, eye irritation.
- Menstrual disturbances.
- Oral contraceptives may become less effective.
- Temporary hearing loss.
- Vertigo (feeling dizzy with a spinning sensation).
- Skin rash, itchy rash, acne, hair loss.
- Enlarged breasts.
- Oral thrush - white, furry, sore tongue and mouth.
- Swelling of hands, ankles or feet.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **ORIZIT PAED 75/50**.

5. How to store ORIZIT PAED 75/50

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep the aluminium sachet in the HDPE container until required for use.

Keep the blister in the carton until required for use.

Store this medicine away from light and moisture. Do not store in the bathroom cabinet.

Any expired or outdated medicines and unused medicines can be returned to your nearest pharmacy.

6. Contents of the pack and other information

What ORIZIT PAED 75/50 contains

The active substances are rifampicin and isoniazid

Each **ORIZIT PAED 75/50** contains rifampicin 75 mg and isoniazid 50 mg

The other ingredients are microcrystalline cellulose, crospovidone, povidone, bleached shellac, croscarmellose sodium, raspberry flavour, magnesium stearate.

Contains aspartame. Sugar free.

What ORIZIT PAED 75/50 looks like and contents of the pack

Brick red mottled, 9.5 mm circular, uncoated biconvex tablets having deep score on one side and plain surface on other side.

HDPE Container:

Tablets are packed in a transparent, self-sealing LDPE polybag and further packed in a silver coloured triple laminated aluminium sachet (LDP/PET/AL), kept in a white plastic container (HDPE), which is sealed at the mouth with an aluminium tagger and is closed with a white HDPE screw-on lid. Pack sizes include 100 tablets.

Alu-alu strip pack:

Tablets are packed in silver-metallic coloured aluminium foil (soft tempered) laminated with low density polyethylene film as the lidding and forming material. The blister is packed in a pre-printed carton. Pack sizes include 28, 56, 84 and 100 tablets.

7 Holder of Certificate of Registration

GROUND FLOOR, BLOCK 1

BASSONIA ESTATE OFFICE PARK (EAST)

1 CUSSONIA DRIVE

BASSONIA ROCK EXT 12

ALBERTON

GAUTENG

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